

## Exhibit 300: Capital Asset Plan and Business Case Summary

### Part I: Summary Information And Justification (All Capital Assets)

#### Section A: Overview

1. **Date of Submission:** 2011-02-28

2. **Agency:** 009

3. **Bureau:** 10

4. **Name of this Investment:** FDA Information and Computing Technologies for the 21st Century (ICT21)

5. **Unique Project (Investment) Identifier (UPI):** 009-10-01-03-01-0031-00

6. **What kind of investment will this be in FY 2012?:** Mixed Life Cycle

- Planning
- Full Acquisition
- Operations and Maintenance
- Mixed Life Cycle
- Multi-Agency Collaboration

7. **What was the first budget year this investment was submitted to OMB?** FY2009

8.

- a. **Provide a brief summary of the investment and justification, including a brief description of how this closes in part or in whole an identified agency performance gap, specific accomplishments expected by the budget year and the related benefit to the mission, and the primary beneficiary(ies) of the investment.**

Development of new information technologies, driven by accelerating computational processing & substantial growth in data volume, is causing transformation to all aspects of the FDA operations. New types & vastly larger quantities of data to be processed by the FDA, from multiple clinical & diagnostic endpoints from industry submissions & collaborations with other research sources, reuse of existing data within & among the FDA centers & other government agencies (i.e. NIH, CMS, CDC, VA, DoD, etc.), & outside entities including foreign countries, are examples of the complexity & number of information sources the FDA handles today. The number of sources & data elements increases as the need for complex inputs for safety evidence & efficacy information, genomics, metabolic network & clinical trials modeling, data markers type data, integrated data & networks, & food imports expands. The FDA is increasing its use of electronic health records data to acquire pertinent information for its pharmacovigilance efforts causing expanded participation in programs & initiatives to define of the records standards & networks to assure appropriate data are gathered for use in such activities as safety & efficacy, & genomics & data markers. To meet these challenges, the FDA is modernizing its capacity & communication capabilities by creating an agency-wide bioinformatics IT platform. The ICT21 Initiative designs & builds this purpose driven, data centric environment for the FDA. The initiative increases the Agency's capabilities to: respond to emerging technologies & challenges, strengthen product development & approval, improve manufacturing & product quality, strengthen post-approval surveillance & safety, support electronic prescribing, & improve clinical decision making. Results are achieved by collecting & combining clinical & other important & pertinent data from industry, government agencies & outside entities into integrated databases & networks to expand the scientific computations & computational sciences at the FDA. The FDA continues to widen the use of analytics for large datasets which integrate multiple clinical & diagnostic endpoints, through increased use of clustering & grid computing to improve collaboration among & within entities interacting with the FDA. The new ICT21 bioinformatics platform supports the FDA's growing mission within 2–10 years & the PMA goal-Expanded e-Government - Disaster Management, & the DHHS goal of increasing scientific R&D.

- b. **Provide any links to relevant websites that would be useful to gain additional information on the**

investment including links to GAO and IG reports.

Title	Link
NONE	

9.

a. **Provide the date of the Agency's Executive/Investment Committee approval of this investment.**

2008-07-21

b. **Provide the date of the most recent or planned approved project charter.** 2007-11-29

10. **Contact information?**

a. **Program/Project Manager Name:** \*

**Phone Number:** \*

**Email:** \*

b. **Business Function Owner Name (i.e. Executive Agent or Investment Owner):** Albaugh, Joe

**Phone Number:** \*

**Email:** \*

11. **What project management qualifications does the Project Manager have? (choose only one per FAC-P/PM or DAWIA):** Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.

- Project manager has been validated according to FAC-P/PM or DAWIA criteria as qualified for this investment.
- Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
- Project manager assigned to investment, but does not meet requirements according to FAC-P/PM or DAWIA criteria.
- Project manager assigned but qualification status review has not yet started.
- No project manager has yet been assigned to this investment.

## Section B: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.B.1: Summary of Funding

(In millions of dollars)

(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

	PY-1 and earlier	PY 2010	CY 2011 (CY Continuing Resolution)	BY 2012	BY+1 2013	BY+2 2014	BY+3 2015	BY+4 and beyond	Total
Planning:	*	*	*	*	*	*	*	*	*
Acquisition:	*	*	*	*	*	*	*	*	*
Planning & Acquisition Government FTE Costs	*	*	*	*	*	*	*	*	*
Subtotal Planning & Acquisition(DME):	*	*	*	*	*	*	*	*	*
Operations & Maintenance:	*	*	*	*	*	*	*	*	*
Disposition Costs (optional):	*	*	*	*	*	*	*	*	*
Operations, Maintenance, Disposition Government FTE Costs	*	*	*	*	*	*	*	*	*
Subtotal O&M and Disposition Costs (SS):	*	*	*	*	*	*	*	*	*
TOTAL FTE Costs	*	*	*	*	*	*	*	*	*
TOTAL (not including FTE costs):	*	*	*	*	*	*	*	*	*
TOTAL (including FTE costs):	*	*	*	*	*	*	*	*	*
Number of FTE represented by	*	*	*	*	*	*	*	*	*

**Table I.B.1: Summary of Funding**  
**(In millions of dollars)**

(Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)

	PY-1 and earlier	PY 2010	CY 2011 (CY Continuing Resolution)	BY 2012	BY+1 2013	BY+2 2014	BY+3 2015	BY+4 and beyond	Total
Costs:									

2. Insert the number of years covered in the column “PY-1 and earlier”: 2

3. Insert the number of years covered in the column “BY+4 and beyond”: \*

4. If the summary of funding has changed from the FY 2011 President’s Budget request, briefly explain those changes:

\*

## Section C: Acquisition/Contract Strategy (All Capital Assets)

1.

Table I.C.1 Contracts Table

Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternative financing	EVM Required	Ultimate Contract Value (M)	Type of Contract/Task Order (Pricing)	Is the contract a Performance Based Service Acquisition (PBSA)?	Effective date	Actual or expected End Date of Contract/Task Order	Extent Competed	Short description of acquisition
Awarded		FY09 - FY11 HHSF223200750011 C: 8A/Small Business Award			*	*	\$0.2	Time and Materials	N	2007-05-15	2009-05-14		
Awarded		FY09 - FY11 HHSF223200750014 C : 8A/Small Business Award - Establish the Service Oriented Architecture framework.			*	*	\$0.4	Time and Materials	N	2007-06-01	2008-11-30		
Awarded		FY09 - FY11 HHSF223200750680 G Project Management Support - Establish ICT21 PMO to manage Bioinformatics initiatives			*	*	\$0.6	Time and Materials	N	2007-10-15	2008-09-30		
Awarded		<a href="#">HHSF223200850016I</a>			*	*	\$3.9	Cost Plus Fixed Fee	Y	2008-09-29		Y	ICT21 PROGRAM IDIQ CONTRACT

Table I.C.1 Contracts Table

Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternative financing	EVM Required	Ultimate Contract Value (M)	Type of Contract/Task Order (Pricing)	Is the contract a Performance Based Service Acquisition (PBSA)?	Effective date	Actual or expected End Date of Contract/Task Order	Extent Completed	Short description of acquisition
Awarded		<a href="#">HHSF223200850017I</a>			*	*	\$35.0	Cost Plus Fixed Fee	N	2008-09-29		Y	ICT21 PROGRAM IDIQ CONTRACT
Awarded		HHS2232008500141			*	*	\$592.4	Firm Fixed Price	Y	2008-09-30	2013-08-31		
Awarded		<a href="#">HHSF223200850020I</a>			*	*	\$0.9	Cost Plus Fixed Fee	N	2008-09-29		Y	ICT21 PROGRAM IDIQ CONTRACT
Awarded		<a href="#">HHSF223200830059C</a>			*	*	\$3.5	Labor Hours	N	2008-09-19	2009-09-21	N	A-123 ASSESSMENT AND IT PROJECT MANAGEMENT SUPPORT
Awarded		<a href="#">HHSF223201000072C</a>			*	*	\$4.6	Cost No Fee	N	2010-09-10	2013-09-19	Y	ARRA::YES::ARRA TAS::75 1701::TAS ARRAOS PACES PART 1
Awarded		HHSF22301002T			*	*	\$5.9	Firm Fixed Price	Y	2010-09-15	2013-01-31		

Table I.C.1 Contracts Table

Contract Status	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	Solicitation ID	Alternative financing	EVM Required	Ultimate Contract Value (M)	Type of Contract/Task Order (Pricing)	Is the contract a Performance Based Service Acquisition (PBSA)?	Effective date	Actual or expected End Date of Contract/Task Order	Extent Completed	Short description of acquisition
Awarded		HHSF223201010159W			*	*	\$0.7	Firm Fixed Price	N	2010-06-18	2010-08-30		
Awarded		HHSF2232008500121 : HHSF22301003T			*	*	\$0.2	Firm Fixed Price	N	2010-09-03	2011-09-06		
Awarded		HHSF223200950173G			*	*	\$0.7	Time and Materials	N	2009-09-17	2010-09-30		
Awarded		HHSN261200800001E: SAIC-F			*	*	\$7.7	Time and Materials	N	2010-07-13	2013-09-30		
Awarded		HHSF223200910192G/GS35F4984H: IBM			*	*	\$1.2	Labor Hours	N	2009-09-18	2010-09-17		
Awarded		HHSF2232009500261 : HHSF22301006T			*	*	\$0.3	Time and Materials	N	2010-09-30	2012-03-31		
Awarded		HHSF2232009500261 : HSF22301002T			*	*	\$1.0	Time and Materials	N	2009-09-17	2010-09-16		
Awarded		HHSF223201010441G			*	*	\$0.2	Time and Materials		2010-09-01	2011-05-31		

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

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\*

3.

- a. Has an Acquisition Plan been developed? If yes, please answer the questions that follow \*
- b. Does the Acquisition Plan reflect the requirements of FAR Subpart 7.1 \*
- c. Was the Acquisition Plan approved in accordance with agency requirements \*
- d. If "yes," enter the date of approval? \*
- e. Is the acquisition plan consistent with your agency Strategic Sustainability Performance Plan? \*
- f. Does the acquisition plan meet the requirements of EOs 13423 and 13514? \*
- g. If an Acquisition Plan has not been developed, provide a brief explanation.

\*



## Part II: IT Capital Investments

### Section A: General

1.
  - a. Confirm that the IT Program/Project manager has the following competencies: configuration management, data management, information management, information resources strategy and planning, information systems/network security, IT architecture, IT performance assessment, infrastructure design, systems integration, systems life cycle, technology awareness, and capital planning and investment control. *yes*
  - b. If not, confirm that the PM has a development plan to achieve competencies either by direct experience or education.
2. Describe the progress of evaluating cloud computing alternatives for service delivery to support this investment.
3. Provide the date of the most recent or planned Quality Assurance Plan
4.
  - a. Provide the UPI of all other investments that have a significant dependency on the successful implementation of this investment.
  - b. If this investment is significantly dependent on the successful implementation of another investment(s), please provide the UPI(s).
5. An Alternatives Analysis must be conducted for all Major Investments with Planning and Acquisition (DME) activities and evaluate the costs and benefits of at least three alternatives and the status quo. The details of the analysis must be available to OMB upon request. Provide the date of the most recent or planned alternatives analysis for this investment. *2008-02-15*
6. Risks must be actively managed throughout the lifecycle of the investment. The Risk Management Plan and risk register must be available to OMB upon request. Provide the date that the risk register was last updated.

## Section B: Cost and Schedule Performance

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Plan Program Mgmt Office	DME	*	\$0.3	\$0.3	2007-05-14	2007-05-14	2007-09-30	2007-09-30	100.00%	100.00%
Establish and implement Program Mgmt Office	DME	*	\$0.9	\$1.0	2007-10-01	2007-10-01	2008-09-30	2008-09-30	100.00%	100.00%
Perform Program Mgmt Functions	DME	*	\$0.9	\$0.7	2008-10-01	2008-10-01	2009-09-30	2009-09-30	100.00%	100.00%
Perform Program Mgmt Functions	DME	*	\$0.8	\$0.2	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
Bioinformatics Transition Plan complete (Phase 1)	DME	*	\$1.3	\$1.2	2007-08-01	2007-07-02	2007-10-31	2008-01-31	100.00%	100.00%
Detailed Alternatives Analysis Complete	DME	*	\$1.0	\$1.1	2007-09-04	2007-08-20	2008-02-28	2008-03-11	100.00%	100.00%
Bioinformatics Transition Plan complete (Phase 2)	DME	*	\$2.6	\$3.0	2007-11-01	2008-07-01	2009-01-30	2009-01-30	100.00%	100.00%
Bioinformatics Recovery site preparation complete	DME	*	\$1.6	\$1.6	2007-07-02	2007-07-02	2008-01-30	2008-04-01	100.00%	100.00%
Bioinformatics design complete	DME	*	\$1.1	\$1.4	2008-01-01	2008-10-01	2008-06-30	2009-08-01	100.00%	100.00%
First Phase - Bioinformatics Platform Migration complete	DME	*	\$17.7	\$15.0	2008-07-01	2008-09-01	2009-07-31	2009-09-01	100.00%	100.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Second Phase - Bioinformatics Platform Migration complete	DME	*	\$16.2	\$15.1	2009-08-03	2009-08-15	2010-03-31	2010-03-31	100.00%	80.00%
Third Phase - Bioinformatics Platform Migration complete	DME	*	\$22.3	\$22.3	2010-04-01	2010-04-01	2010-12-31	2010-12-31	100.00%	100.00%
FY09 Operations and Maintenance Support	SS	*	\$3.8	\$3.8	2009-08-03	2009-09-01	2009-09-30	2009-09-30	100.00%	100.00%
FY10 Operations and Maintenance Support	SS	*	\$5.1	\$1.3	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
Decommission of Parklawn Data Center	SS	*	\$1.5	\$1.5	2011-01-01	2011-01-01	2011-03-31	2011-04-29	100.00%	100.00%
FY11 DR - Requirements Gathering and Design of Business Continuity Planning (BCP) and Disaster Recovery (DR) Strategies - Delivery findings document to the COTR	DME	*	\$0.1		2011-10-01		2011-12-01		0.00%	0.00%
FY11 DR - Implementation Labor to Stand up the effective Methods as detailed in the BCP and DR	DME	*	*	*	2012-05-01	*	2012-08-30	*	*	*

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
plans										
FY12 DR - Design, Planning, and Implementation of Retirement of Older Existing or Overlapping BCP or DR Plans, Systems, Software or Hardware - Culminates in lists of legacy hardware and software retired from the FDA infrastructure	DME	*	*	*	2012-07-01	*	2012-09-30	*	*	*
FY11 SE - Scientific Enclave Planning/Scoping Support	DME	*	\$0.3	\$0.2	2010-10-01	2010-10-01	2011-09-30		75.00%	75.00%
FY12 SE - Scientific Enclave Planning/Scoping Support	DME	*	\$0.3		2011-10-01		2012-09-30		0.00%	0.00%
FY 10 HPC – GOVT DME Cost	DME	*	\$0.4	\$0.4	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
FY 10 HPC - Information Scientist ORISE	DME	*	\$0.6	\$0.6	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
FY 10 HPC - GOV FTE - Project Management	SS	*	\$0.3	\$0.3	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
FY 10 HPC - O&M	SS	*	\$0.9	\$0.9	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
FY 11 HPC –	DME	*	\$0.4	\$0.0	2010-10-01	2010-10-01	2011-09-30		0.00%	0.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
GOVT DME Cost										
FY 11 HPC - GOVT FTE Project Management	SS	*	\$0.3	\$0.2	2010-10-01	2010-10-01	2011-09-30		75.00%	75.00%
FY 11 HPC - Project Management Support	SS	*	\$0.3	\$0.2	2010-10-01	2010-10-01	2011-09-30		75.00%	75.00%
FY 11 HPC - GOVT FTE Information Scientist	DME	*	\$0.8	\$0.0	2010-10-01	2011-06-01	2011-09-30		75.00%	25.00%
FY 11 HPC - O&M	SS	*	\$0.9	\$0.0	2010-10-01	2010-10-01	2011-09-30		0.00%	0.00%
FY 12 HPC – GOVT DME Cost	DME	*	\$0.4		2011-10-01		2012-09-30		0.00%	0.00%
FY 12 HPC - GOVT FTE Project Management	SS	*	\$0.3		2011-10-01		2012-09-30		0.00%	0.00%
FY 12 HPC - Project Management Support	SS	*	\$0.3		2011-10-01		2012-09-30		0.00%	0.00%
FY 12 HPC - GOV FTE Information Scientist	DME	*	\$0.8		2011-10-01		2012-09-30		0.00%	0.00%
FY 12 HPC - O&M	SS	*	\$0.9		2011-10-01		2012-09-30		0.00%	0.00%
FY 12 HPC – HW Acquisitions	DME	*	\$0.5		2011-10-01		2012-09-30		0.00%	0.00%
FY 13 HPC - GOV DME Cost	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY 13 HPC -	SS	*	*	*	2012-10-01	*	2013-09-30	*	*	*

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
GOV FTE - Project Management										
FY 13 HPC - Project Management Support	SS	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY 13 HPC - GOV FTE - Information Scientist	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY 13 HPC - O&M	SS	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY 13 HPC - Acquisition	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY 14 HPC - GOV DME Cost	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY 14 HPC - GOV FTE - Project Management	SS	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY 14 HPC - Project Management Support	SS	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY 14 HPC - GOV FTE - Information Scientist	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY 14 HPC - O&M	SS	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY10 PCOR - Project Management Support	DME	*	\$0.6	\$0.6	2010-06-01	2010-06-01	2010-09-30	2010-09-30	100.00%	100.00%
FY10 PCOR -	DME	*	\$0.9	\$0.9	2010-07-01	2010-07-01	2010-09-30	2010-09-30	100.00%	100.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Research Repository - Phase I (Acquisition)										
FY11 PCOR - Project Management Support	DME	*	\$0.7	\$0.1	2010-10-01	2010-10-01	2011-09-30		75.00%	75.00%
FY11 PCOR - Legacy - Identification of data studies/Pilots	DME	*	\$0.3	\$0.3	2010-10-01	2010-10-01	2011-03-31	2011-02-28	100.00%	100.00%
FY11 PCOR - Research Repository - Phase II (Hardware/Software Installation)	DME	*	\$0.1	\$0.1	2010-10-01	2010-10-01	2011-02-28	2011-02-28	86.00%	100.00%
FY11 PCOR - PACES (PACES PCOR Training Program for scientific exchanges)	DME	*	\$0.2	\$0.1	2010-10-01	2010-10-01	2011-03-31	2011-03-31	100.00%	100.00%
FY11 PCOR - Research Repository - Phase III (Development/Test)	DME	*	\$0.1	\$0.0	2011-03-01	2011-03-01	2011-09-30		34.00%	17.00%
FY11 PCOR - Legacy - Convert Data Studies - CBER	DME	*	\$0.8	\$0.3	2011-04-01	2011-02-02	2011-06-30	2011-06-30	100.00%	100.00%
FY11 PCOR - PACES (Scientific Computing)	DME	*	\$1.1	\$0.3	2011-04-01	2011-04-01	2011-09-30		50.00%	50.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Strategies for PCOR and Analysis Methodologies - Study 1)										
FY11 PCOR - Project Management Support	SS	*	\$0.0		2011-05-01		2011-09-30		40.00%	0.00%
FY11 PCOR - Legacy - Convert Data Studies - CDRH	DME	*	\$0.8	\$0.2	2011-07-01	2011-02-08	2011-09-30		0.00%	75.00%
FY11 PCOR - Legacy - Convert Data Studies - CDER	DME	*	\$0.8	\$0.2	2011-07-01	2011-02-11	2011-09-30		0.00%	75.00%
FY12 PCOR - Project Management Support FY12	SS	*	\$0.0		2011-10-01		2012-09-30		0.00%	0.00%
FY12 PCOR - Project Management Support	DME	*	\$0.2		2011-10-01		2012-09-30		0.00%	0.00%
FY12 PCOR - Legacy - Convert Data Studies - CDER	DME	*	\$0.9		2011-10-01		2011-12-31		0.00%	0.00%
FY12 PCOR - Research Repository - Phase IV (Operational)	SS	*	\$0.5		2011-10-01		2012-09-30		0.00%	0.00%
FY12 PCOR - PACES (Evaluate and Develop Comparative	DME	*	\$1.1		2011-10-01		2012-04-30		0.00%	0.00%



Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Innovative Clinical trial Design Strategies - Study 1)										
FY12 PCOR - Legacy - Convert Data Studies - CBER	DME	*	*	*	2012-01-01	*	2012-03-31	*	*	*
FY12 PCOR - Legacy - Convert Data Studies - CDRH	DME	*	*	*	2012-04-01	*	2012-06-30	*	*	*
FY12 PCOR - PACES (Scientific Computing Strategies for PCOR and Analysis Methodologies - Study 2)	DME	*	*	*	2012-05-01	*	2012-09-30	*	*	*
FY12 PCOR - Legacy - Convert Data Studies - CDER	DME	*	*	*	2012-07-01	*	2012-09-30	*	*	*
FY13 PCOR - Project Management Support FY13	SS	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 PCOR - Research Repository-Phase IV (Operational) FY13	SS	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 PCOR - Project Management	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Support FY13										
FY13 PCOR - Legacy - Convert Data Studies - CDER	DME	*	*	*	2012-10-01	*	2013-01-31	*	*	*
FY13 PCOR - PACES (Evaluate and Develop Comparative Innovative Clinical trial Design Strategies - Study 2)	DME	*	*	*	2012-10-01	*	2013-09-15	*	*	*
FY14 PCOR - Project Management Support FY14	SS	*	*	*	2013-10-01	*	2013-12-31	*	*	*
FY14 PCOR - Research Repository-Phase IV (Operational) FY14	SS	*	*	*	2013-10-01	*	2013-12-13	*	*	*
FY14 PCOR - Project Management Support FY14	DME	*	*	*	2013-10-01	*	2013-12-30	*	*	*
FY10 JANUS - Integrate Nonclinical Studies - Data Validation and Load Service - 2010	DME	*	\$0.1	\$0.1	2009-10-01	2009-10-01	2010-06-30	2010-06-30	100.00%	100.00%
FY10 JANUS - Integrate Pharmacogenomic Data - Data Validation and	DME	*	\$0.1	\$0.1	2009-10-01	2009-10-01	2010-06-30	2010-06-30	100.00%	100.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Load Service - 2010										
FY10 JANUS - Clinical Trial Repository - Phase 3A Pilot	DME	*	\$1.1	\$1.1	2009-10-01	2009-10-01	2010-08-31	2010-08-31	100.00%	100.00%
FY11 JANUS - Government FTE PM Support - 2011	DME	*	\$0.3	\$0.2	2010-10-01	2010-10-01	2011-09-30		75.00%	75.00%
FY11 JANUS - Planning: Platform Hosting AA	DME	*	\$0.5	\$0.0	2010-10-01	2010-10-01	2011-09-30		75.00%	0.00%
FY11 JANUS - Interface to Janus - CDER	DME	*	\$0.2	\$0.1	2010-10-01	2010-10-01	2011-09-30		75.00%	75.00%
FY11 JANUS - Maintenance: ToxVision, and Janus Servers (@ NCTR)	SS	*	\$0.0	\$0.0	2010-10-01	2010-10-01	2011-09-30		75.00%	75.00%
FY11 JANUS - Clinical Trial Repository - Deliver Skeleton Working Architecture	DME	*	\$1.5	\$0.3	2011-05-01	2011-05-01	2011-09-30		40.00%	40.00%
FY12 JANUS - Clinical Trial Repository - Deliver operational system into staging area	DME	*	\$3.1		2011-10-01		2012-09-30		0.00%	0.00%
FY12 JANUS - Government FTE PM Support -	DME	*	\$0.3		2011-10-01		2012-09-30		0.00%	0.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
2012										
FY12 JANUS - Data Standards Testing: Data Validation and Load Services	DME	*	\$0.3		2011-10-01		2012-09-30		0.00%	0.00%
FY12 JANUS - Janus Terminology – 2012	DME	*	\$0.3		2011-10-01		2012-09-30		0.00%	0.00%
FY12 JANUS - Interface to Janus - CDER 2012	DME	*	\$0.2		2011-10-01		2012-09-30		0.00%	0.00%
FY12 JANUS - Maintenance: ToxVision, and Janus Servers (@ NCTR)	SS	*	\$0.0		2011-10-01		2012-09-30		0.00%	0.00%
FY13 JANUS - Clinical Trial Repository - Deliver enhanced data analysis capability and automated operations	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 JANUS - Government FTE PM Support - 2013	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 JANUS - IT Support: FTE -2013	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 JANUS - Planning: Strategic Plan, Modeling, Platform Hosting,	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Study Data Analysis 2013										
FY13 JANUS - Prepare CONOPS: CDER, CBER, CDRH, CVM	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 JANUS - Integrate Nonclinical Studies - Data Validation and Load Service	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 JANUS - Data Standards Testing: Source e-File Respository (RIM)	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 JANUS - Integrate Pharmacogenomic Data - Data Validation and Load Service	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 JANUS - Janus Terminology - 2013	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY13 JANUS - Interface to Janus - all other centers 2013	DME	*	*	*	2012-10-01	*	2013-09-30	*	*	*
FY14 JANUS - Government FTE PM Support - 2014	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY14 JANUS - IT	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Support: FTE -2014										
FY14 JANUS - O&M: FTE - 2014	SS	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY14 JANUS - Planning: Strategic Plan, Modeling, Platform Hosting, Study Data Analysis 2014	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY14 JANUS - Prepare CONOPS: CTP, CFSAN	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY14 JANUS - Integrate Nonclinical Studies - Janus Nonclinical Data Repository	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY14 JANUS - Data Standards Testing: Data Extraction and Transformation Services	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY14 JANUS - Integrate Pharmacogenomic Data - Janus PGX Data Repository	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY14 JANUS - Janus Terminology - 2014	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY14 JANUS -	DME	*	*	*	2013-10-01	*	2014-09-30	*	*	*

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Interface to Janus - all other centers 2014										
FY14 JANUS - Maintain Janus 2014	SS	*	*	*	2013-10-01	*	2014-09-30	*	*	*
FY15 JANUS - Government FTE PM Support - 2015	DME	*	*	*	2014-10-01	*	2015-09-30	*	*	*
FY15 JANUS - IT Support: FTE -2015	DME	*	*	*	2014-10-01	*	2015-09-30	*	*	*
FY15 JANUS - O&M: FTE - 2015	SS	*	*	*	2014-10-01	*	2015-09-30	*	*	*
FY15 JANUS - Planning: Strategic Plan, Modeling, Study Data Analysis 2015	DME	*	*	*	2014-10-01	*	2015-09-30	*	*	*
FY15 JANUS - Integrate Nonclinical Studies - Data Extraction/Reporting/Access Service	DME	*	*	*	2014-10-01	*	2015-09-30	*	*	*
FY15 JANUS - Data Standards Testing: Data Extraction and Transformation Services - 2015	DME	*	*	*	2014-10-01	*	2015-09-30	*	*	*
FY15 JANUS - Integrate Pharmacogenomic Data - Data	DME	*	*	*	2014-10-01	*	2015-09-30	*	*	*

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Extraction/Reporting/Access Service										
FY15 JANUS - Janus Terminology - 2015	DME	*	*	*	2014-10-01	*	2015-09-30	*	*	*
FY15 JANUS - Interface to Janus - all other centers 2015	DME	*	*	*	2014-10-01	*	2015-09-30	*	*	*
FY15 JANUS - Maintain Janus 2015	SS	*	*	*	2014-10-01	*	2015-09-30	*	*	*
FY16 JANUS - Government FTE PM Support - 2016	DME	*	*	*	2015-10-01	*	2016-09-30	*	*	*
FY16 JANUS - IT Support: FTE -2016	DME	*	*	*	2015-10-01	*	2016-09-30	*	*	*
FY16 JANUS - O&M: FTE - 2016	SS	*	*	*	2015-10-01	*	2016-09-30	*	*	*
FY16 JANUS - Planning: Strategic Plan, Modeling, Study Data Analysis 2016	DME	*	*	*	2015-10-01	*	2016-09-30	*	*	*
FY16 JANUS - Integrate Nonclinical Studies - Data Extraction/Reporting/Access Service - 2016	DME	*	*	*	2015-10-01	*	2016-09-30	*	*	*
FY16 JANUS - Janus	DME	*	*	*	2015-10-01	*	2016-09-30	*	*	*



Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Terminology - 2016										
FY16 JANUS - Maintain Janus 2016	SS	*	*	*	2015-10-01	*	2016-09-30	*	*	*
FY09 JANUS - Planning: Kick-off Study Data Standards Dev	DME	*	\$0.0	\$0.0	2009-09-21	2009-09-21	2009-09-30	2009-09-30	100.00%	100.00%
FY09 JANUS - Planning: Kick-off Current & Future-State Modeling	DME	*	\$0.0	\$0.0	2009-09-21	2009-09-21	2009-09-30	2009-09-30	100.00%	100.00%
FY10 JANUS - Planning: CDER CONOPS	DME	*	\$1.2	\$1.2	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
FY10 JANUS - Planning: Budget, Strategic Plan, Current State Modeling	DME	*	\$0.7	\$0.7	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
FY10 JANUS - Planning: Data Standards Proof of Concept Testing	DME	*	\$0.9	\$0.9	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%
FY09 FDA Contracted Hosted Data Center (Private Cloud)	DME	*	\$52.1	\$52.1	2008-10-01	2008-10-01	2009-09-30	2009-09-30	100.00%	100.00%
FY10 FDA Contracted Hosted Data Center (Private Cloud)	DME	*	\$56.3	\$56.3	2009-10-01	2009-10-01	2010-09-30	2010-09-30	100.00%	100.00%

Table II.B.1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline:

Description of Activity	DME or SS	Agency EA Transition Plan Milestone Identifier	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
FY11 FDA Contracted Hosted Data Center (Private Cloud)	DME	*	\$56.9	\$42.6	2010-10-01	2010-10-01	2011-09-30		75.00%	75.00%
FY12 FDA Contracted Hosted Data Center (Private Cloud)	DME	*	\$57.9		2011-10-01		2012-09-30		0.00%	0.00%

2. If the investment cost, schedule, or performance variances are not within 10 percent of the current baseline, provide a complete analysis of the reasons for the variances, the corrective actions to be taken, and the most likely estimate at completion.

3. For mixed lifecycle or operations and maintenance investments an Operational Analysis must be performed annually. Operational analysis may identify the need to redesign or modify an asset by identifying previously undetected faults in design, construction, or installation/integration, highlighting whether actual operation and maintenance costs vary significantly from budgeted costs, or documenting that the asset is failing to meet program requirements. The details of the analysis must be available to OMB upon request. Insert the date of the most recent or planned operational analysis.

4. Did the Operational analysis cover all 4 areas of analysis: Customer Results, Strategic and Business Results, Financial Performance, and Innovation?

Section C: Financial Management Systems

Table II.C.1: Financial Management Systems			
System(s) Name	System acronym	Type of Financial System	BY Funding
*	*	*	*

Section D: Multi-Agency Collaboration Oversight (For Multi-Agency Collaborations only)

Table II.D.1. Customer Table:	
Customer Agency	Joint exhibit approval date
NONE	

Table II.D.2. Shared Service Providers		
Shared Service Provider (Agency)	Shared Service Asset Title	Shared Service Provider Exhibit 53 UPI (BY 2011)
*	*	*

Table II.D.3. For IT Investments, Partner Funding Strategies (\$millions):							
Partner Agency	Partner exhibit 53 UPI (BY 2012)	CY Monetary Contribution	CY “In-Kind” Contribution	CY Fee-for-Service	BY Monetary Contribution	BY “In-Kind” Contribution	BY Fee-for-Service
NONE							

Table II.D.4. Legacy Systems Being Replaced		
Name of the Legacy Investment of Systems	Current UPI	Date of the System Retirement
*	*	*

## Section E: Performance Information

Table I.E.1a. Performance Metric Attributes

Measurement Area (For IT Assets)	Measurement Grouping (For IT Assets)	Measurement Indicator	Reporting Frequency	Unit of Measure	Performance Measure Direction	Baseline	Year Baseline Established for this measure (Origination Date)
Processes and Activities	Efficiency	Increase number of cross-study analysis conducted	annual	Number	Increase	0	2011-09-01
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2012	BY12: 3			2010-09-16
			2013	BY12: 3			2010-09-16
			2014	BY12: 3			2010-09-16
			2015	BY12: 3			2010-09-16
			2016	BY12: 3			2010-09-16
			2017	BY12: 3			2010-09-16
Mission and Business Results	Population Health Management and Consumer Safety	Increase number of public health related comparative effectiveness topics researched	annual	Number	Increase	0	2010-09-01
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2012	BY12: 2			2010-09-16

Customer Results	Customer Satisfaction	Increase reviewer satisfaction for using tools to retrieve and perform standard pre-specified analyses on structured scientific data	2013	BY12: 2			2010-09-16
			2014	BY12: 2			2010-09-16
			2015	BY12: 2			2010-09-16
			2016	BY12: 2			2010-09-16
			2017	BY12: 2			2010-09-16
			annual	Number (scale of 1.0-5.0)	Increase	1.25	2010-09-01
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2012	Increase satisfaction score by 15%			2010-09-16
			2013	Increase satisfaction score by 15%			2010-09-16
			2014	Increase satisfaction score by 15%			2010-09-16
			2015	Increase satisfaction score by 15%			2010-09-16
			2016	Increase satisfaction score by 15%			2010-09-16
			2017	Increase satisfaction score by 15%			2010-09-16
Technology	Interoperability	Increase the number of data sources used to	annual	Number	Increase	0	2010-09-01

		inform or support analysis of study data in the Janus repository					
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2012	BY12: 1 (Enterprise Vocabulary Services)			2010-09-16
			2013	BY12: 1 (Enterprise Vocabulary Services)			2010-09-16
			2014	BY12: 1 (Enterprise Vocabulary Services)			2010-09-16
			2015	BY12: 1 (Enterprise Vocabulary Services)			2010-09-16
			2016	BY12: 1 (Enterprise Vocabulary Services)			2010-09-16
			2017	BY12: 1 (Enterprise Vocabulary Services)			2010-09-16
Mission and Business Results	Population Health Management and Consumer Safety	Increase the number of studies for which structured data are validated and stored within the Janus repository for decision making and regulatory review	annual	Number	Increase	0	2010-09-01
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
			2012	BY12: 10			2010-09-16
			2013	BY12: 10			2010-09-16
			2014	BY12: 10			2010-09-16
			2015	BY12: 10			2010-09-16

			2016	BY12: 10				2010-09-16
			2017	BY12: 10				2010-09-16
Processes and Activities	Participation	Increase the number of users that are using tools that access and utilize study data in the repository	annual	Number	Increase	0		2011-09-01
			Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"		Last Updated
			2012	BY12: 15 (Based on average of 5 users per Center for CDER, CBER, and CDRH.)				2010-09-16
			2013	BY12: 15 (Based on average of 5 users per Center for CDER, CBER, and CDRH.)				2010-09-16
			2014	BY12: 15 (Based on average of 5 users per Center for CDER, CBER, and CDRH.)				2010-09-16
			2015	BY12: 15 (Based on average of 5 users per Center for CDER, CBER, and CDRH.)				2010-09-16
			2016	BY12: 15 (Based on average of 5 users per Center for CDER, CBER, and CDRH.)				2010-09-16
			2017	BY12: 15 (Based on average of 5 users per Center for CDER, CBER, and CDRH.)				2010-09-16
Customer Results	Customer Impact or Burden	Increase the percentage of FDA submissions that	annual	Percent	Increase	0		2010-09-01



adhere to FDA-published  
validation rules

Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
2012	To be measured by 9/1/2011			2010-09-16
2013	To be measured by 9/1/2011			2010-09-16
2014	To be measured by 9/1/2011			2010-09-16
2015	To be measured by 9/1/2011			2010-09-16
2016	To be measured by 9/1/2011			2010-09-16
2017	To be measured by 9/1/2011			2010-09-16

Processes and Activities	Efficiency	Reduce the time needed for reviewers to retrieve and perform a standard prespecified analysis on structured scientific data	annual	Days	Decrease	25	2011-09-01
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Fiscal Year	Target	Actual Results	Target "Met" or "Not Met"	Last Updated
2012	Reduce average time by 15%			2010-09-16
2013	Reduce average time by 15%			2010-09-16
2014	Reduce average time by 15%			2010-09-16
2015	Reduce average time by 15%			2010-09-16
2016	Reduce average time by 15%			2010-09-16

2017	Reduce average time by 15%			2010-09-16
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\* - Indicates data is redacted.